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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/194,396	12/08/1998	JAN HOLGERSSON	45115-53906	3163

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/194,396	Applicant(s) HOLGERSSON ET AL.	
	Examiner G. R. Ewoldt, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2003 and 28 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-23, 26 and 28-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-23, 26 and 28-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendments and remarks, filed 11/19/03 and 1/28/04, have been entered.
2. Claims 21-23, 26, and 28-38 are being acted upon.
3. Applicant's affirmation of the election of group I (previously Claims 21-26 and 28), without traverse, is acknowledged.
4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claim 28 stands rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons of record as set forth in the paper, mailed 11/20/01 and maintained in the paper mailed 11/12/02. This is a new matter rejection.

Specifically, "The fusion protein of Claim 21, wherein the first polypeptide comprises more Gal α 1,3Gal epitopes than (now the human) a wild-type P-selectin glycoprotein ligand-1." (Claim 28).

Applicant's arguments, filed 11/19/03, have been fully considered but they are not persuasive. Applicant argues that support can be found for the claim at page 11, lines 12-37 of the specification. Applicant further argues that as now amended, "Applicants assert that the recitation of the phrase "the human wild-type P-selectin glycoprotein ligand-1 polypeptide" is a single species, and thus, that one skilled in the art could

readily determine if the claimed polypeptide falls within its scope".

Applicant is advised that the example discloses just a single species of the claimed fusion polypeptide. As set forth previously, disclosure of a single species comprises insufficient support for claims drawn to a genus. Further, it is unclear how asserting that the skilled artisan could "readily determine if the claimed polypeptide falls within its [the claimed invention's] scope" is intended to rebut a rejection for the introduction of new matter into the claims.

6. Claims 21-23, 26, and 28-38 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons of record as set forth in the paper mailed 11/12/02. This is a new matter rejection.

Specifically:

A) "the second polypeptide comprises an immunoglobulin heavy chain polypeptide." (Claim 21, 26, and 29),

B) "wherein the first polypeptide comprises the extracellular portion of a P-selectin glycoprotein ligand-1 ..." (Claim 29),

C) "wherein the first polypeptide comprises more Gal α 1,3Gal epitopes than a wild-type P-selectin glycoprotein ligand-1." (Claim 33 and 38)

D) "wherein the first polypeptide comprises a part of a P-selectin glycoprotein ligand-1 that mediates binding to selectin ..." (Claim 34).

Applicant's arguments, filed 11/19/03, have been fully considered but they are not persuasive.

Regarding A), Applicant argues that the specification discloses "Fc part (hinge, CH2 and CH3) of mouse IgG_{2b}" and "It is known to one of ordinary skill in the art that the Fc (fragment crystallizable) region of an IgG inherently contains an immunoglobulin heavy chain polypeptide, particularly since the immunoglobulin light chain polypeptide is not present in the Fc region, as it is contained within the F(ab) region of an IgG."

Applicant appears to be confused regarding the structure of immunoglobulins. An Fc fragment is a piece of an Ig heavy chain. Thus, one could say that the Ig heavy chain inherently contains the Fc fragment, but not vice versa. Applicant appears to be even more confused regarding the Ig light chain. An Ig light chain would contain an F(ab) fragment, because an F(ab) fragment is part of an Ig light chain, but again, not vice versa. Note too that an Ig heavy chain would also contain an F(ab) fragment.

Regarding B), Applicant argues that "the specification at page 8, lines 6-8, recites that "[t]he mucin/immunoglobulin expression plasmid was constructed by fusing the PCR-amplified cDNA of the extracellular part of PSGL-1 in frame via a BamHI site".

Applicant is advised that, as set forth previously, disclosure of a single species comprises insufficient support for claims drawn to a genus. Thus, the specification teaches a construct of PSGL-1/mouse IgG_{2b}, but not the generic construct of the claim.

Regarding C), see section 5 above.

Regarding D), Applicant again indicates support at page 4, lines 34-36 and page 5, lines 6-9.

Applicant is advised that, the specification discloses PSGL-1 and "an essential part" of PSGL-1, but not a part of PSGL-1 "that mediates binding to selectin".

7. The following are New Grounds for Rejection.

8. Claims 28, 33, and 38 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

Specifically, "the human wild-type P-selectin glycoprotein ligand-1" (Claims 28, 33, and 38) is not found in the specification.

Applicant indicates that support for the new limitation can be found at page 8, lines 3-6 of the specification.

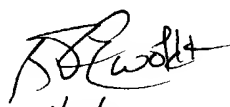
Page 8, lines 3-6 of the specification discloses only a specific construct that is insufficient support for the generic claims.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

11. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

G.R. Ewoldt, Ph.D.
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4/13/04
G.R. EWOLDT, PH.D.
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